## SECOND REGULAR SESSION

## SENATE BILL NO. 666

## 100TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR WHITE.

Pre-filed December 1, 2019, and ordered printed.

3020S.02I

ADRIANE D. CROUSE, Secretary.

## AN ACT

To repeal section 208.227, RSMo, and to enact in lieu thereof two new sections relating to antipsychotic drugs.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Section 208.227, RSMo, is repealed and two new sections

- 2 enacted in lieu thereof, to be known as sections 208.226 and 208.227, to read as
- 3 follows:
  - 208.226. 1. No restrictions to access shall be imposed that
- 2 preclude availability of any individual antipsychotic medication.
- 2. The provisions of this section shall not prohibit the division
- 4 from utilizing clinical edits to ensure clinical best practices including,
- 5 but not limited to:
- 6 (1) Drug safety and avoidance of harmful drug interactions;
- 7 (2) Compliance with nationally recognized and juried clinical
- 8 guidelines from national medical associations using medical evidence
- 9 and emphasizing best practice principles;
- 10 (3) Detection of patients receiving prescription drugs from
- 11 multiple prescribers; and
- 12 (4) Detection, prevention, and treatment of substance use
- 13 disorders.
- 14 3. The division shall issue a provider update no less than twice
- 15 annually to enumerate treatment and utilization principles for MO
- 16 HealthNet providers including, but not limited to:
- 17 (1) Treatment with antipsychotic drugs, as with any other form
- 18 of treatment, should be individualized in order to optimize the patient's

SB 666 2

19 recovery and stability;

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- 20 (2) Treatment with antipsychotic drugs should be as effective, 21 safe, and well-tolerated as supported by best medical evidence;
- 22 (3) Treatment with antipsychotic drugs should consider the 23 individual patient's needs, preferences, and vulnerabilities;
- 24 (4) Treatment with antipsychotic drugs should support an 25 improved quality of life for the patient; and
  - (5) Treatment choices should be informed by the best current medical evidence and should be updated consistent with evolving nationally recognized best practice guidelines.
  - 4. If the division implements any new policy or clinical edit for an antipsychotic drug, the division shall continue to allow MO HealthNet participants access to any antipsychotic drug that they utilize and on which they are stable or that they have successfully utilized previously. The division may recommend a resource list with no restrictions to access.
- 208.227. 1. [No restrictions to access shall be imposed that preclude availability of any individual atypical antipsychotic monotherapy for the treatment of schizophrenia, bipolar disorder, or psychosis associated with severe depression.] The division shall establish a pharmaceutical case management or polypharmacy program for high risk MO HealthNet participants with numerous or multiple prescribed drugs. The division shall also establish a behavioral health pharmacy and opioid surveillance program to encourage the use of best medical evidence-supported prescription practices. The division shall communicate with providers, as such term is defined in section 208.164, whose prescribing practices deviate from or do not otherwise utilize best medical evidence-supported prescription practices. The communication may be telemetric, 11 written, oral, or some combination thereof. These programs shall be established 12and administered through processes established and supported under a 13 14 memorandum of understanding between the department of mental health and the 15 department of social services, or their successor entities.
- 16 2. The provisions of this section shall not prohibit the division from 17 utilizing clinical edits to ensure clinical best practices including, but not limited 18 to:
- 19 (1) Drug safety and avoidance of harmful drug interactions;
- 20 (2) Compliance with nationally recognized and juried clinical guidelines

SB 666 3

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21 from national medical associations using medical evidence and emphasizing best 22practice principles;

- 23 (3) Detection of patients receiving prescription drugs from multiple prescribers; and 24
  - (4) Detection, prevention, and treatment of substance use disorders.
- 26 3. [The division shall issue a provider update no less than twice annually to enumerate treatment and utilization principles for MO HealthNet providers 27 including, but not limited to: 28
- 29 (1) Treatment with antipsychotic drugs, as with any other form of 30 treatment, should be individualized in order to optimize the patient's recovery 31 and stability;
  - (2) Treatment with antipsychotic drugs should be as effective, safe, and well-tolerated as supported by best medical evidence;
- 34 (3) Treatment with antipsychotic drugs should consider the individual 35 patient's needs, preferences, and vulnerabilities;
- (4) Treatment with antipsychotic drugs should support an improved 36 37 quality of life for the patient;
  - (5) Treatment choices should be informed by the best current medical evidence and should be updated consistent with evolving nationally recognized best practice guidelines; and
  - (6) Cost considerations in the context of best practices, efficacy, and patient response to adverse drug reactions should guide antipsychotic medication policy and selection once the preceding principles have been maximally achieved.
- 44 4. If the division implements any new policy or clinical edit for an 45 antipsychotic drug, the division shall continue to allow MO HealthNet participants access to any antipsychotic drug that they utilize and on which they 46 are stable or that they have successfully utilized previously. The division shall adhere to the following: 48
- 49 (1) If an antipsychotic drug listed as "nonpreferred" is considered clinically appropriate for an individual patient based on the patient's previous 50 response to the drug or other medical considerations, prior authorization 51 52 procedures, as such term is defined in section 208.164, shall be simple and 53 flexible:
- 54 (2) If an antipsychotic drug listed as "nonpreferred" is known or found to be safe and effective for a given individual, the division shall not restrict the 55 56 patient's access to that drug. Such nonpreferred drug shall, for that patient only

SB 666 4

57 and if that patient has been reasonably adherent to the prescribed therapy, be 58 considered "preferred" in order to minimize the risk of relapse and to support 59 continuity of care for the patient;

- 60 (3) A patient shall not be required to change antipsychotic drugs due to 61 changes in medication management policy, prior authorization, or a change in the 62 payor responsible for the benefit; and
- 63 transferring from (4) Patients state psychiatric hospitals community-based settings, including patients previously found to be not guilty of 64 a criminal offense by reason of insanity or who have previously been found to be 65 66 incompetent to stand trial, shall be permitted to continue the medication regimen 67 that aided the stability and recovery so that such patient was able to successfully 68 transition to the community-based setting.
- 69 5. The division's medication policy and clinical edits shall provide MO HealthNet participants initial access to multiple Food and Drug 70 71Administration-approved antipsychotic drugs that have substantially the same clinical differences and adverse effects that are predictable across individual 73 patients and whose manufacturers have entered into a federal rebate agreement with the Department of Health and Human Services. Clinical differences may 7475include, but not be limited to, weight gain, extrapyramidal side effects, sedation, susceptibility to metabolic syndrome, other substantial adverse effects, the 76 77availability of long-acting formulations, and proven efficacy in the treatment of psychosis. The available drugs for an individual patient shall include, but not be 78 79 limited to, the following categories:
- 80 (1) At least one relatively weight-neutral atypical antipsychotic 81 medication;
- 82 (2) At least one long-acting injectable formulation of an atypical 83 antipsychotic;
  - (3) Clozapine;

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- 85 (4) At least one atypical antipsychotic medication with relatively potent 86 sedative effects;
  - (5) At least one medium-potency typical antipsychotic medication;
- 88 (6) At least one long-acting injectable formulation of a high-potency 89 typical antipsychotic medication;
- 90 (7) At least one high-potency typical antipsychotic medication; and
- 91 (8) At least one low-potency typical antipsychotic medication.
- 92 6. Nothing in subsection 5 of this section shall be construed to require any

SB 666 5

93 of the following:

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- 94 (1) Step therapy or a trial of a typical antipsychotic drug before 95 permitting a patient access to an atypical drug or antipsychotic medication;
- 96 (2) A limit of one atypical antipsychotic drug as an open-access, 97 first-choice agent; or
- 98 (3) A trial of one of the eight categories of drugs listed in subsection 5 of 99 this section before having access to the other seven categories.
- 100 7.1 The department of social services may promulgate rules and 101 regulations to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the 102 103 authority delegated in this section shall become effective only if it complies with 104 and is subject to all of the provisions of chapter 536 and, if applicable, section 105 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the 106 107 effective date, or to disapprove and annul a rule are subsequently held 108 unconstitutional, then the grant of rulemaking authority and any rule proposed 109 or adopted after August 28, 2017, shall be invalid and void.
- [8.] 4. The department shall submit such state plan amendments and waivers to the Centers for Medicare and Medicaid Services of the federal Department of Health and Human Services as the department determines are necessary to implement the provisions of this section.
  - [9. As used in this section, the following terms mean:
- 115 (1) "Division", the MO HealthNet division of the department of social 116 services;
- 117 (2) "Reasonably adherent", a patient's adherence to taking medication on 118 a prescribed schedule as measured by a medication position ratio of at least 119 seventy-five percent;
- 120 (3) "Successfully utilized previously", a drug or drug regimen's provision 121 of clinical stability in treating a patient's symptoms.]

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